IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC., and BAYER HEALTHCARE LLC,	)	
Plaintiffs,	)	
v.	)	**C.A. No. 05-349-GMS**
BAXTER INTERNATIONAL INC., and BAXTER HEALTHCARE CORPORATION,	)	**Jury Trial Demanded**
Defendants.	)	
BAXTER HEALTHCARE CORPORATION,	)	
Counterclaimant,	)	**REDACTED VERSION DI 238**
v.	)	
TALECRIS BIOTHERAPEUTICS, INC., and BAYER HEALTHCARE LLC,	)	
Counterdefendants.	)	

PLAINTIFFS' BRIEF IN OPPOSITION TO THE MOTION FOR SUMMARY JUDGMENT FILED BY BAXTER INTERNATIONAL INC. AND BAXTER HEALTHCARE CORPORATION

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

Rules and Statutes

I. INTRODUCTION

Baxter's Motion is a transparent effort to infuse ambiguity into simple claim language. There is no dispute that Baxter's GAMMAGARD® LIQUID product has an acceptable level of anticomplement activity ("ACA") suitable for intravenous administration, and that it is safe for use with patients. Nor is there any evidence to suggest that Baxter was ever in doubt about what constitutes an acceptable ACA level for its product. Yet Baxter inconsistently argues that a person skilled in the art would not know when an ACA level is acceptable. In fact, as experts from both sides have agreed, one skilled in the art does know when a product is safe and has an acceptable ACA level, based at least in part on FDA release specifications and prior art methods.

Baxter also takes issue with the Court's claim construction, effectively seeking reconsideration. As it attempted to do during claim construction, Baxter would have the Court import numeric limits into Claim 1 of the '191 patent and require the use of a specific assay to measure ACA in accordance with numeric limits. Baxter once again argues that the increase in ACA must be to a specific numeric level -- an "unacceptable" level, an argument already rejected by the Court. Baxter raises nothing new on this Motion to justify a different result.

Nor does the absence of a numeric limitation render Claim 1 indefinite. Every manufacturer, through its own testing and analysis, understands whether its product has an acceptable level of ACA. The FDA, armed with extensive clinical data for each product and process, then confirms for every IGIV manufacturer that its product has an acceptable level of ACA. Baxter's argument that "[b]ecause the boundary for acceptability is not fixed [in the claim], ***a manufacturer could never know*** if its product has an 'acceptable level' of ACA" (Docket Item ("D.I.") 231, p.21 (emphasis added))[1] is contrary to Baxter's own experience, and

[1] D.I. 231 is Baxter's Opening Brief in Support of Summary Judgment Motion.

requires that the Court ignore the incontrovertible facts relating to the knowledge of those skilled in the art.

Honeywell Int'l, Inc. v. Int'l Trade Comm'n, 341 F.3d 1332 (Fed. Cir. 2003) squarely establishes that Claim 1 is not "insolubly ambiguous." A key difference between the claim at issue in *Honeywell* and Claim 1 of the '191 patent-in-suit is that, consistent with the subject matter at issue, the *Honeywell* claim contained a specific numeric range and it therefore required a specific test method to yield a precise numeric value. In contrast, Claim 1 of the '191 patent does not contain a numeric range, nor is one necessary. It therefore does not require a specific test method. Moreover, unlike the present case, *Honeywell* was based on a key fact finding that the involved measurement methodology was "critical" to the determination of whether the numeric limitation in the claim was met, and the *Honeywell* patent specification was silent about the different methods. Here, there is neither a fact finding of criticality nor silence in the specification about how ACA may be measured.

Equally important, and distinct from the facts in *Honeywell,* Claim 1 of the '191 patent requires a measurement of ACA to determine ***relative*** ACA levels -- simply an increase followed by a reduction. There are different prior art methods, well known to persons skilled in the art, to measure this increase and reduction. Correlating the results of ACA testing across different methodologies or across different products is unnecessary and irrelevant for a person skilled in the art to determine whether a product has an ACA level "suitable for intravenous administration." Indeed, Baxter did no such thing before representing to the FDA that its product had ACA levels suitable for intravenous use.

There are also established tests published in the art that one of ordinary skill knows can be used to measure ACA for release of a finished ("final") product. This "acceptable" release limit

for ACA is determined based on an exchange of information between the manufacturer and the regulatory authorities for that particular product and process. Based on this information, grounded on demonstrated clinical results, the FDA and the manufacturer arrive at an ACA release specification for the particular product that is an objective, conservative standard of acceptability for that particular product and process. Every expert in this case agreed with these facts. In short, to understand the scope of Claim 1, it is not necessary for Claim 1 to recite particular numeric limits of acceptability based on a particular test for a particular product. Because of the nature of the testing methodology and differences in IGIV products and processes, the imposition of such a range would unfairly and unnecessarily limit Claim 1.

In addition, under Baxter's arguments, there exist genuine issues of material fact that need to be tried. *See infra*, pp.31-32. For example, the proper methodology for testing ACA of in-process samples, the determination of one of ordinary skill in the art, and the role of adverse events in establishing FDA ACA guidelines are in dispute. For this reason alone, Baxter's Motion for Summary Judgment should be denied.

II. NATURE AND STAGE OF PROCEEDINGS

This case was brought by Talecris Biotherapeutics, Inc. and Bayer Healthcare LLC (collectively, "Plaintiffs") against Baxter International Inc. and Baxter Healthcare Corporation (collectively, "Baxter") for infringement of U.S. Patent No. 6,686,191 ("the '191 patent"). On August 25, 2006, Plaintiffs filed a motion to disqualify Baxter's current counsel. D.I. 76. This motion is *sub judice*. The Court conducted a *Markman* hearing on December 14, 2006, and issued its claim construction ruling on December 28, 2006 (D.I. 199), construing all claim terms disputed by the parties. Thus, Baxter's Motion must be assessed through the lens of the Court's claim construction.

On February 1, 2007, Baxter sought permission to file motions for summary judgment of: (1) non-infringement; (2) invalidity under 35 U.S.C. § 112, ¶ 1 (written description), and (3) invalidity of the '191 patent under 35 U.S.C § 112, ¶ 2 (indefiniteness). D.I. 212. On February 22, 2007, the Court issued an order refusing to permit Baxter to file motions on non-infringement and written description but allowed Baxter's motion on alleged indefiniteness. D.I. 226. Thus, neither written description nor infringement is at issue at this time. The Court also directed that both sides "squarely address the impact" of the *Honeywell* case and other relevant and related case law. *Id.*

Expert discovery closed on March 7, 2007. Baxter filed its opening brief on March 8, 2007 (D.I. 231) in support of its motion for summary judgment (D.I. 230). A mediation conference is scheduled before Magistrate Judge Thynge for May 11, 2007. A Pretrial Conference is scheduled for June 11, 2007. A jury trial is scheduled to begin July 9, 2007. This is Plaintiffs' Brief in Opposition to the Motion for Summary Judgment Filed by Baxter.[2]

III. SUMMARY OF THE ARGUMENT

1. Every manufacturer of IGIV products knows what an acceptable ACA level suitable for intravenous administration is, and every expert in this case had no problem understanding its meaning. Baxter does not and cannot dispute that its GAMMAGARD® LIQUID product has an acceptable ACA level.

2. Claim 1 of the '191 patent has no numeric limits, and the absence of such does not render the claim indefinite.

[2] We refer herein to the exhibits attached to the Declaration of Jaclyn M. Mason ("Mason Declaration") contained in the Appendix to this brief as Decl. Ex. ___, ___. We also refer to the Joint Appendix to Claim Construction Brief filed at D.I. 161 as "JA___", and we incorporate it by reference herein as part of the Appendix to this brief.

3. Claim 1 just requires measurement of relative ACA levels - - an increase followed by a reduction. This measurement does not require a numeric limit in the claim, or a specific test. As a corollary, it does not require an increase to a given unacceptable level.

4. An acceptable ACA level suitable for intravenous administration is based on final product measurements. This measurement is specific for each product and is determined by the assay used for that specific product, as one skilled in the art knows. A comparison between testing methods is not necessary to determine the scope of Claim 1.

5. Assays used to measure ACA are taught in the '191 patent and in published prior art, including art cited in the prosecution history, as those skilled in the art recognize, and the use of these methods was known to those skilled in the art.

6. The *Honeywell* case is materially different than this case. It involved a claim with specific numeric limits, and measurement methods were critical to the determination of these numeric limits. The measurement method urged by the patentee was not published in the art and appeared only in in-house confidential documents. Here, there has been no fact finding of criticality and here ACA measurements are known and published in the art and in the patent specification. Here, unlike *Honeywell*, a relative determination must be made, and all experts have acknowledged that persons skilled in the art readily know when products have acceptable ACA levels, as evidenced, for example, by their approval for use in humans after clinical evaluation.

IV. STATEMENT OF FACTS

A. THE '191 PATENT CLAIMS, SPECIFICATION, AND PROSECUTION HISTORY ESTABLISH THAT CLAIM 1 IS DEFINITE.

Claim 1, the only independent claim of the '191 patent and the sole claim at issue for purposes of this motion, claims a process for making intravenously administrable immune serum globulin ("ISG"), also referred to as intravenous immune globulin or IGIV.

Claim 1 reads as follows:

> A method of treating a solution of antibodies which may have virus activity, the method comprising
>
> a) contacting the solution with a trialkylphosphate and a detergent under conditions sufficient to substantially reduce any virus activity and resulting in an increased level of anticomplement activity; and
>
> b) then incubating the solution of step a) under conditions of controlled time, pH, temperature, and ionic strength, such that the increased anticomplement activity of the solution is reduced to an acceptable level suitable for intravenous administration.

Decl. Ex.1, 11:34-44.

The '191 specification provides a detailed written description of each of the claim elements, and presents numerous examples fully exemplifying their ordinary meaning. For example, Table 1 illustrates the increase in ACA as a result of a viral inactivation step involving treatment with solvent/detergents (Claim 1, step a)). *Id.* at 6:45-7:4. Tables 3, 5, 6 and 7 illustrate the reduction in ACA levels as a result of a controlled incubation step (Claim 1, step b)). *Id.* at 8:55-9:37. The specification also describes, as examples for the patentee's 5% and 10% IGIV solutions, preferences for acceptable levels of ACA suitable for intravenous administration: "[F]or a 5% ISG formulation the acceptable level suitable for intravenous administration preferably would be less than about 45 CH_{50} units/mL, and more preferably less than about 30 CH_{50} units/mL. For a 10% ISG formulation, the acceptable level suitable for intravenous

administration preferably would be less than about 60 CH_{50} units/mL, and more preferably less than about 45 CH_{50} units/mL." *Id.* at 5:57-64. These preferable ACA levels for the patentee's products derive from a hemolytic assay, a well established test for measuring ACA levels that was available at the time the '191 application was filed. The specification refers to the Palmer and Whaley reference (reference 19)[3] and the Kabat and Meyer reference (reference 20)[4] for a more detailed description of a hemolytic assay. *Id.* at 6:3-4.

While those skilled in the art, as shown below, would be aware of other methods to determine both relative and absolute levels of ACA in a particular product, the face of the issued patent and specification (*id.* at 1:61-64) also refers to the Yang reference (reference 17)[5] which describes another widely recognized ACA test, the C1q binding assay.[6] The Yang reference appears throughout the prosecution history. Thus, Baxter's contention that the '191 intrinsic record does not provide "any detail" as to ACA testing methods (D.I. 231, p.19) is unsupported.

The '191 prosecution history further confirms that precise numeric limitations are unnecessary to understand the bounds of Claim 1. In the application for the '191 patent, step a) of Claim 1 originally stated: "resulting in ***a given*** level of anticomplement activity" and "an acceptable level suitable for intravenous administration". JA28 (emphasis added). In the First Office Action, the examiner initially rejected the claim as indefinite. JA35. The phrase "an increase" was ultimately substituted for "given level," and the examiner then withdrew the rejections, agreeing that Claim 1 was definite. *See* JA35, 77, 80, 83, 88, 98, 109.

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[3] Palmer, D. F. and Whaley, S. D., *Complement Fixation Test*, in Manual of Clinical Laboratory Immunology (Ed. N. R. Rose, et al., American Society for Microbiology, Washington, D.C., 1986) pp. 57-66.
[4] Mayer, M. M., *Quantitative C'Fixation Analysis*, Complement and Complement Fixation, in Experimental Immunochemistry (Ed. E. A. Kabat and M. M. Meyer, Thomas, Springfield, Ill., 1961), pp. 214-216, 227-228.
[5] Yang, Y.H.J. *et al.*, "Antibody Fc Functional Activity of Intravenous Immunoglobulin Preparations Treated with Solvent-Detergent for Virus Inactivation, *Vox Sang* 67:337-344 (1994).
[6] Baxter's expert Dr. Kindt readily agreed that **REDACTED**
Decl. Ex. 5, 75:9-14; *see also* Decl. Ex. 4, 328:19-329:7.

B. THE COURT'S CLAIM CONSTRUCTION WAS ENTIRELY PROPER AND DOES NOT RENDER THE '191 CLAIMS INSOLUBLY AMBIGUOUS.

On December 28, 2006, the Court issued its definitive claim construction ruling, rejecting Baxter's proposed constructions and adopting the "plain and ordinary meaning" of most claim terms.[7] *See* D.I. 199.[8] Baxter nonetheless contends that while most of the terms have their plain and ordinary meaning, they really have no meaning at all. Baxter asserts that the following claim terms are insolubly ambiguous and indefinite: (1) "increased level of anticomplement activity"; (2) "then incubating the solution of step a)"; (3) "increased anticomplement activity of the solution"; and (4) "acceptable level suitable for intravenous administration." We will not repeat the arguments made by the parties and the Court's decision uniformly rejecting Baxter's arguments. For ease of reference, however, we refer the Court to the Claim Construction Summary, which is Exhibit 15 of the Mason Declaration filed herewith (*see, supra*, n.2).

C. THE EXPERT TESTIMONY AND PRIOR ART ESTABLISHES THAT PERSONS SKILLED IN THE ART WOULD UNDERSTAND WHAT IS "ACCEPTABLE" BASED PRIMARILY ON PRODUCT APPROVAL.

1. Suitability For Intravenous Administration

The determination of whether IGIV products are suitable for intravenous administration to patients (which includes having an "acceptable ACA level") is based primarily on regulatory processes. *See* Decl. Ex. 11, p.4. Although the responsibility for recommending release specifications rests largely with the individual manufacturer, approval of the specifications rests with the FDA and is based on the review of extensive clinical data. *Id.*

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[7] The Court stated, "'In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.'" D.I. 199, p.2 n.1 (citation omitted).

[8] D.I. 199 is the Order Construing the Terms of U.S. Patent No. 6,686,191.

Plaintiffs' clinical expert, Dr. Erwin Gelfand, explained the process by which clinical data are used to assess and establish safety parameters for a given product, how clinical experience is used to perfect process and product specifications (Decl. Ex. 2, 143:22-145:25, 149:4-18), and why and how modifications may be made over time as more information is gathered (*id.* at 199:20-206:15). This basic clinical process involving individual patients is followed for all FDA regulated pharmaceuticals in the United States. It is through this process that ACA release specifications are created. *Id.* at 197:18-198:8. Baxter's suggestion that "acceptability varies from patient to patient" (D.I. 231, pp.13-14, 20-21) is grossly misleading. The specifications for acceptable ACA levels for a manufacturing process are necessarily derived from clinical studies that necessarily evaluate individuals, as part of a population of patients. Decl. Ex. 2, 143:22-144:8. Through analysis of these clinical data, an objective standard is established for an acceptable ACA level. *See id.* at 196:13-19.[9]

That FDA release limits are, as Baxter admits, "product-specific" and "vary from manufacturer to manufacturer and from product to product" (D.I. 231, p.20) does not render the term "acceptable level suitable for intravenous administration" indefinite. This process is followed for every drug sold in the United States, and one skilled in the art would readily understand these procedures just as Dr. Gelfand has explained them. *See* Decl. Ex. 2, 206:9-15. Each specific product has an ascertainable, well-defined, FDA approved specification, unique to the particular manufacturing process, which is the proxy for acceptable ACA levels.[10]

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[9] Moreover, that pharmaceutical release specifications are constantly being evaluated (D.I. 231, p.22) to continually assure safety hardly establishes that "acceptability" is ill-defined or meaningless. This process is consistent with standard practice followed by all pharmaceutical companies. Just because a standard may change does not diminish its status as a standard.

[10] Baxter argues that before a manufacturer has obtained FDA approval and final release limits are established, there is no standard for a manufacturer to determine if it infringes (D.I. 231, p.21). This contention completely ignores the drug development and regulatory process, which is designed to assure product safety.

Within this indisputable context, all of the pertinent experts in the case, Baxter's and Plaintiffs', uniformly agreed that if a regulatory agency approves an IGIV product, that product is "acceptable" for intravenous administration. Decl. Ex. 2, 123:7-12, 34:15-19, 130:8-16, 185:13-16, 141:3-9.

Even Baxter's infringement expert, Dr. Snape, testified:

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Decl. Ex. 7, 135:5-12; *see id.* at 133:25-134:11. Dr. Snape further confirmed that

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Decl. Ex. 8, 187:9-188:7.

Baxter's invalidity expert, Dr. Kindt, like Dr. Snape, also understood the meaning of "acceptable." Dr. Kindt was readily able to determine whether the prior art met the "acceptable level suitable for intravenous administration" claim element. For example,

REDACTED

Dr.

Kindt specifically stated that

REDACTED

Id. at 93:4-19. Indeed, he concluded that

REDACTED

Id. at 115:10-15.

Id. at 118:23-119:4.

REDACTED

Decl. Ex. 3, 190:16-19; *see also id.* at 183:7-16, 189:13-19, 212:8-213:16.

Baxter's statements that "no one knows what is meant by key phrases in the claims" (D.I. 231, p.1), "not a single person" knows what acceptable means (*id.* at p.9), and there is "insufficient definition in either the '191 patent or the knowledge in the art" (*id.* at p.19) are contradicted by the testimony of all of these experts. Contrary to Baxter's position (*id.*), there are in fact "identifiable standards" to determine acceptable ACA levels. In fact, it is the goal of every manufacturer -- including Baxter – to have a safe product having an acceptable ACA level.

As to Baxter's misleading out-of-context snippet from Dr. Ravetch's deposition (*id.* at pp.1, 13), Dr. Ravetch repeatedly stated that

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See Decl. Ex. 3, 181:7-182:3, 183:23-184:5, 184:19-20, 185:6-10, 187:6-8, 189:3-8, 189:22-190:2, 190:7-11, 191:21-24, 192:10-12, 198:18-20, 198:25-199:2, 199:6-7, 199:11-12, 199:21-23, 206:11-22, 210:9-16, 213:23-214:4.

REDACTED

See id. at 185:8-10, 185:23-25, 186:13-15, 187:13-16.

2. Release Limits And ACA Assays

The record in this case unequivocally establishes that product release criteria are uniquely tailored for each IGIV product, the specific process by which it is made, and the particular ACA assay used. As such, a comparison or correlation of data obtained from different assays is never necessary. The determination of acceptability is "paired" with the assay used for that particular product and process. One of ordinary skill in the art would understand that release specifications, and thus acceptability, are a customized assessment for each manufacturer and product. Dr. Gelfand testified,

REDACTED

Decl. Ex. 2, 168:12-21, *see also id.* at 129:7-8, 195:10-196:2, 144:22-23. Baxter's manufacturing expert, Dr. Snape, testified that **REDACTED** . Decl. Ex. 7, 39:12-14.

REDACTED . *Id.* at 40:23-41:3; Decl. Ex. 4, 398:23-399:8; Decl. Ex. 2, 129:7-8, 144:22-145:13. Baxter's contention that Claim 1 is invalid because ACA release limits vary depending on the test used and the technician who ran it (D.I. 231, p.3) conflicts with the FDA validation process by which release limits are strictly controlled.

Furthermore, one of ordinary skill in the art understands that different assays exist and the choice of assay will also depend on the precise experimental conditions that are being evaluated. Decl. Ex. 4, 328:19-329:7. Both parties' experts agreed that in the United States, the ACA release limits for a given IGIV product are individually determined by the manufacturer with final approval from the FDA. *Accord* D.I. 231, p.21; Decl. Ex. 2, 207:1-208:17, 122:7-13; Decl. Ex. 8, 186:3-11; Decl. Ex. 4, 274:14-275:5.[11] Baxter admits the same in its opening brief stating, "FDA release limits are product-specific…and, consequently, vary from manufacturer to manufacturer and from product to product." D.I. 231, p.20.

In summary, as those skilled in the art recognize, the subject matter of IGIV does not permit precise, numeric cross-product, cross-process, and cross-assay comparisons. *See* Decl. Ex. 5, 96:25-97:21. But such comparisons are not needed for a given manufacturer to understand whether its process and product fall within the scope of Claim 1. Both sides' experts readily understood the ordinary meaning of "acceptable level suitable for intravenous administration" to one skilled in the art. Both sides' experts agreed that the prior art and the '191 specification taught ACA measurement methods. And both sides' experts agreed that ACA is strictly controlled by the FDA imposition of release limits specific to each particular IGIV product.

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[11] Baxter's suggestion that Dr. Gelfand limited his definition of acceptability to the specific release limits exemplified in the '191 patent (D.I. 231, p.9, n.2) is wrong. Dr. Gelfand clearly indicated that **REDACTED** Decl. Ex. 2, 206:9-15. Baxter's own prosecution history summary (D.I. 231, p.10) confirms that Dr. Gelfand's reading is correct. The statements in the specification are, as Dr. Gelfand observed, clearly referred to as "examples" and preferences.

V. APPLICABLE LAW

A. BAXTER'S BURDEN ON SUMMARY JUDGMENT

A court may grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). A fact is material if it might affect the outcome of the suit. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). An issue is genuine if a reasonable jury could possibly find in favor of the non-moving party with regard to that issue. *Id.* at 249. In determining whether there is a genuine issue of material fact, a court should review the evidence, including expert testimony, and construe all inferences in the light most favorable to the non-moving party. *See Goodman v. Mead Johnson & Co.*, 534 F.2d 566, 573 (3d Cir. 1976).

B. THE LAW OF INDEFINITENESS

An issued patent is presumed valid, 35 U.S.C. § 282, and the party challenging validity bears the burden of proving indefiniteness by clear and convincing evidence. *See Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990). Clear and convincing evidence is evidence that "could place in the ultimate fact finder an abiding conviction that the truth of [the] factual contentions [is] 'highly probable.'" *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984).

Title 35 U.S.C. § 112, ¶ 2, provides that "the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. "A determination of claim

indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." *Personalized Media Commc'ns, LLC. v. ITC*, 161 F.3d 696, 705 (Fed. Cir. 1998). "A claim is ***definite*** if 'one skilled in the art would understand the bounds of the claim when read in light of the specification.'" *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1383 (Fed. Cir. 2005) (quoting *Personalized Media*, 161 F.3d at 705) (emphasis added). However, as is well-established under § 112 ¶ 1, a specification need not disclose what is well known in the art. *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004) (citation omitted). Contrarily, a claim is ***indefinite*** only "'if reasonable efforts at claim construction prove futile,' that is, if a claim 'is insolubly ambiguous, and no narrowing construction can properly be adopted.'" *Invitrogen*, 424 F.3d at 1383 (quoting *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1376 (Fed. Cir. 2001)) (emphasis added). As long as the boundaries of a claim may be reasonably understood, invalidity for indefiniteness will be avoided. *Invitrogen*, 424 F.3d at 1383; *see also Xerox Corp. v. 3Com Corp.*, 458 F.3d 1310, 1323 (Fed. Cir. 2006).[12]

The fact that claims are intended to cover the use of an invention with various types of products makes no difference if the claim terms at issue are "as accurate as the subject matter permits." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986). Indeed, "[t]he degree of precision necessary to satisfy § 112 depends upon the subject matter and cannot be viewed in the abstract." *E.I. Dupont De Nemours & Co. v. Millennium Chem., Inc.*, No. 97-237, 1999 U.S. Dist. LEXIS 12447, at *8 (D. Del. Aug. 2, 1999) (*see* Decl. Ex. 14).

[12] The Federal Circuit has held, "If a claim is subject to construction, *i.e.*, it is not insolubly ambiguous, it is not invalid for indefiniteness." *Bancorp Servs. L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372 (Fed. Cir. 2004); *see also Praxair, Inc. v. ATMI, Inc.*, No. 03-1158, 2005 U.S. Dist. LEXIS 29843, at *5 (D. Del. Nov. 28, 2005) ("Because the court was able to construe the limitation 'at about the axial midpoint,' the claims are definite, as a matter of law.") (*see* Decl. Ex. 12); *Mallinckrodt, Inc. v. Masimo Corp.*, No. 00-6506, 2004 U.S. Dist. LEXIS 28518, at *68-69 (C.D. Cal. Jul. 12, 2004), *aff'd in part, rev'd in part*, 147 Fed. Appx. 158 (Fed. Cir. 2005), *cert. dismissed*, 126 S. Ct. 1294 (U.S. 2006) (*see* Decl. Ex. 13). Consequently, if a claim has been construed in accordance with its plain and ordinary meaning, it is neither "insolubly ambiguous" nor indefinite.

As this Court properly observed in its claim construction order, quoting from the Federal Circuit in *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998), "when a claim term is expressed in general descriptive words, we will not ordinarily limit the term to a numeric range that may appear in the written description or in other claims". D.I. 199, p.2 n.2. A claim does not need to express quantitative or numeric terms for it to be definite. The Federal Circuit has also held, "[A] patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement." *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1341 (Fed. Cir. 2003); *In re Marosi*, 710 F.2d 799, 802-03 (Fed. Cir. 1983). In *Marosi*, the Federal Circuit held that the term "essentially free of alkali metal" was not indefinite where the specification defined it as containing only residual impurities, such as 4 ppm. *Id.* at 802. Marosi disclaimed a level of 3819 ppm disclosed in the prior art, and the PTO took the position that one skilled in the art would not know where to draw the line between 4 ppm and 3819 ppm when making the "essentially free" determination. *Id.* However, the Federal Circuit agreed with Marosi, explaining that his invention "does not reside in such a number" and that a skilled artisan would draw that line between unavoidable impurities and essential ingredients. *Id.* at 803.

Moreover, courts have held that the use of functional claim terms such as "enhancing amount" and "physiologically acceptable" are not indefinite, provided one of ordinary skill in the art could determine the bounds of the claims without undue experimentation. *Tristrata Tech., Inc. v. ICN Pharms., Inc.*, 313 F. Supp. 2d 405, 410 (D. Del. 2004); *Pharmacia & Upjohn Co. v. Sicor Inc.*, 447 F. Supp. 2d 363, 370 (D. Del. 2006); *see generally Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1383-84 (Fed. Cir. 2003) ("Our predecessor court has stated that "effective amount" is a common and generally acceptable term for pharmaceutical

claims and is not ambiguous or indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation.") (citation omitted). In *Orthokinetics*, the Federal Circuit held that a claim limitation specifying that a certain part of a pediatric wheelchair be "so dimensioned as to be insertable through the space between the doorframe of an automobile and one of the seats" was definite. 806 F.2d at 1576. The Court stated that the phrase "so dimensioned" is as accurate as the subject matter permits, noting that the patent law does not require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone they be listed in the claims. *Id.*

VI. ARGUMENT

A. *HONEYWELL* SUPPORTS VALIDITY OF THE '191 PATENT.

In *Honeywell,* the Federal Circuit upheld a final determination of the ITC that Honeywell's patent was indefinite. 341 F.3d at 1334. The patent claimed a process for production of a particular type of yarn ("PET"). *Id.* The issue focused on the method to measure one element of the claims – the melting point elevation ("MPE"). *Id.* at 1335. All of the independent claims required that the drawn or undrawn yarns have an MPE within a prescribed numerical range. *Id.*

The Federal Circuit, relying on the ITC's key factual finding that the choice of the measurement method was "critical" in discerning whether a particular product is made by a process that infringes the patent claims, noted that neither the claims, the written description, nor the prosecution history referenced any method that could be used to measure the MPE. *Id.* at 1339. The Court therefore held that the claims were insolubly ambiguous and indefinite. *Id.* at 1340.

In its brief, Baxter improperly relies on *Honeywell* as a case providing multiple test methods, where the specification does not provide any detail as to which test method was used or which method should be used. (D.I. 231, p.19). However, the factual situation before the Court in this case is materially different from the facts in *Honeywell*.

First, there is a key difference between the '191 patent and the patent-at-issue in *Honeywell*: Claim 1 of the '191 patent does ***not*** specify any numeric ACA values, while ***all*** the claims in the *Honeywell* patent claim a specified numeric MPE range. Moreover, in *Honeywell* neither the intrinsic evidence nor any written publication compelled a narrowing to any one particular method as urged by *Honeywell*. 341 F.3d at 1339. Here, both the elevation and reduction in ACA level for a given product can be determined by a number of well-recognized methods published and known in the art. And Baxter's position that Claim 1 must be limited to only one method and that numeric limits, like Honeywell's ball method construction rejected by the Federal Circuit, must thereby be imported, is contradicted by both the '191 specification, the published prior art, and the testimony of ***both*** sides' experts.

Second, in the '191 patent, unlike in *Honeywell*, the particular assay used to measure ACA is not "critical" because there are ***no numeric ACA values*** in Claim 1. In the absence of a numeric range, the '191 claims simply do not require the type of selection required in *Honeywell*. It does not matter if numerical ACA values obtained using different assays cannot be compared. All that is required in Claim 1 is that the ACA increase, decrease and, in the end, that the ACA level of the final product is at an acceptable level suitable for intravenous administration. So long as the same assay is used to measure the step a) increase and step b) decrease (as was done in the '191 patent), no "cross-assay comparison" is necessary. Additionally, the increase and decrease in ACA required by Claim 1 are ***relative comparisons***. The precise numeric value of the increase

and decrease is not specified and need not be specified in Claim 1. In other words, there is no need for numerical ACA values in Claim 1 to determine whether one skilled in the art would understand the bounds of the claim when read in light of the specification.

In contrast to this case, *Honeywell* did not involve a relative determination. Instead, the *Honeywell* claims required a precise, absolute numeric value to assess whether the MPE was within the claimed numeric range. Additionally, in this case, unlike in *Honeywell*, the determination of whether the ACA level in the final container is acceptable is a measurement that is dependent upon using an assay that is approved by the FDA or other regulatory authorities for the particular product and process that is being tested. There is no dispute that this level can readily be determined, and that it is in fact determined by all IGIV manufacturers.

Third, the Federal Circuit relied on the ITC's key factual finding that the measurement methods at issue were "critical" in discerning whether a particular product is made by a process that infringed the *Honeywell* patent claims. *Id.* In *Honeywell,* the specification failed to set forth any method by which the testing could be conducted; the intrinsic evidence did not compel a narrowing of the claims to any one particular method; the *Honeywell* claims, written description, and prosecution history did not mention the different methods or provide sufficient clues to discern which methods were acceptable; and the method urged by the patentee was not published in the art. *Id.* Unlike the situation in *Honeywell*, the '191 patent discloses a testing methodology, hemolytic assays (CH_{50} values) and C1q assays (*see* the Yang reference cited in the '191 patent and discussed throughout the prosecution history on other points; *see also* Decl. Ex. 5, 75:9-14; Decl. Ex. 4, 328:19-329:7); and the prior art specifies other testing methodologies known in the art.

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REDACTED Decl. Ex. 5, 75:2-8, 99:10-12, 111:3-5. Unlike *Honeywell*, there has been no factual finding in this case that the choice of the testing method is critical to discerning whether an IGIV solution has been produced using the claimed '191 process (nor can there be, since the choice of test method is not critical). And unlike *Honeywell*, both sides' experts have testified about, and applied, established measurement methods taught in the art.[13]

Fourth, in *Honeywell*, the Federal Circuit rejected each of the possible claim constructions because the intrinsic evidence failed to give the Court any guidance as to how one of ordinary skill in the art would interpret the requirements of the claim. 341 F.3d at 1340. The Federal Circuit was compelled to reject Honeywell's proffered method because (1) it was not described in publicly available documents, (2) it ignored other available methods, (3) it was supported only by Honeywell's expert testimony, and (4) it was only documented in Honeywell's proprietary documents. *Id.* at 1340-41. The Federal Circuit explicitly ruled that Honeywell's construction required importation outside the bounds of the claims, the written description, and the prosecution history, ***and outside the scope of any written publication***. *Id.* at 1341. Here, multiple test methods are supported by the intrinsic evidence, the prior art, and the testimony of experts for both sides. *See supra*, pp.7, 21.

Based on all of these factual differences, *Honeywell* does not require that the Court hold the '191 patent Claim 1 invalid for indefiniteness. Rather, *Honeywell* establishes that Baxter's numeric limitation and single measurement method argument should be rejected and that summary judgment should be denied. In this case, where no numeric limitation is contained

[13] As noted in the Claim Construction Summary (Decl. Ex. 15), the Court has properly rejected during claim construction Baxter's invitation to import into Claim 1 the hemolytic assay testing method and thereby limit Claim 1 to a single method. The Court also properly rejected Baxter's corollary construction seeking to import numeric limitations into Claim 1 which could only then be determined by Baxter's only one testing method construction. *See* D.I. 231, p.9 n.2 (numeric limits required).

within Claim 1, where a single testing method is absent from Claim 1, and the where multiple testing methods are available, the claim is not rendered indefinite.

B. THE RECORD IN THIS CASE ESTABLISHES THAT THE '191 CLAIM TERMS ARE DEFINITE AS A MATTER OF LAW AND BAXTER'S ARGUMENTS SHOULD BE REJECTED.

The claims, the written description, and the prosecution history of the '191 patent establish the definiteness of Claim 1. *See supra*, pp.6-8. The extrinsic evidence, particularly the testimony of both parties' experts, also proves that these claim terms are definite. *See supra*, pp.9-14; *see also Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002), *remanded to* 395 F. Supp. 2d 558 (E.D. Mich. 2005).

1. The Term "Acceptable Level Suitable For Intravenous Administration" Is Definite.

The Court construed "acceptable level suitable for intravenous administration" to have its plain and ordinary meaning. D.I. 199, p.4. Baxter argues that this claim term has no meaning and is indefinite. Baxter contends that the only construction that ***could give*** the term definiteness would be to import the numeric preferences from the specification as determined solely by the particular assay used by the inventor. D.I. 231, p.9 n.2. Plaintiffs disagree.

First, Baxter improperly relies on the testimony of the inventor and prosecuting attorney. *Id.* at 10-13. The Federal Circuit has held that "it is particularly inappropriate to consider inventor testimony obtained in the context of litigation in assessing validity under section 112, paragraph 2, in view of the absence of probative value of such testimony." *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379 (Fed. Cir. 2000) (holding that the inventor's deposition testimony could not be used to invalidate the patent claims under § 112, ¶ 2). Thus, Baxter's reliance on Dr. Alonso's testimony (D.I. 231, pp.11-13) is a red herring. The same reasoning holds true with the prosecuting attorney, Mr. James Giblin (*id.* at p.12). *See generally Bell &*

Howell Document Mgmt. Prods. v. Altek Sys., 132 F.3d 701, 706 (Fed. Cir. 1997). However, even Dr. Alonso and Mr. Giblin recognized, consistent with the expert testimony in this case, that acceptability depends on many factors (D.I. 231, pp.12-13). Likewise, Baxter's reliance on the prosecution history to support its position is misplaced since the examiner considered the claims to be definite. *See supra*, p.8.

Second, contrary to Baxter's arguments (D.I. 231, p.13), both parties' experts unanimously testified (*see supra*, pp.10-12) that persons of ordinary skill in the art would know that when injecting immune globulin intravenously, ACA must be at an acceptable level. The experts also explained that persons skilled in the art would know how to determine whether an ACA level is acceptable and how to use a validated assay to assure that this level is achieved for every batch of its product that is sold. Baxter's indefiniteness argument cannot be squared with reality. One need only review the ACA release limits and assays used for exemplary commercial products. These specifications confirm the use and understanding of release limits and assays by one skilled in the art. We also note that in *Pharmacia*, Judge Jordan had no problem construing the analogous phrase "physiologically acceptable" as, *inter alia*, suitable for administration to humans. 447 F. Supp. 2d at 370. The patent in this case relates to ACA and requires that ACA be at an acceptable level suitable for intravenous administration to humans. One of ordinary skill in the art would readily recognize that if an ACA level of a product is suitable for release under standards set by regulatory agencies, the ACA level of that product is necessarily at an "acceptable level suitable for intravenous administration". This is confirmed by the experts, the prior art, and the evidence relating to the state of the art. *See supra*, pp.10-12.

Third, there are well-recognized and accepted methods for measuring ACA which were known to one of ordinary skill in the art at the time of filing of the '191 application. The '191

specification describes the hemolytic assay and cites the Yang reference which exemplifies the C1q binding assay. *See supra*, pp.7, 21. In addition, prior art references relied upon by Baxter, such as Tsay and Ng, discuss the C4a assay. *See supra*, p.21.

Baxter's use of the Rousell paper to argue that different ACA assays for the same product cannot be compared (D.I. 231, pp.15-16) is: (1) a red herring; and (2) misleading. As stated before, because comparison across assays is irrelevant, the '191 patent does not require such a comparison. The ACA testing is just used to show relative increases and decreases and an ACA level for the final product that is acceptable for intravenous administration. In any event, one of the assays in Rousell was not designed for the product being tested. Decl. Ex. 9, 85:12-86:24

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Compare Decl. Ex. 7, 40:23-41:3; Decl. Ex. 4, 398:23-399:8; Decl. Ex. 2, 129:7-8, 144:22-145:13.

Fourth, Baxter's arguments (D.I. 231, pp.23-24) regarding the correlation of adverse events to ACA levels also do not pass muster. Elevated ACA is undesirable, and it has been historically associated with various adverse events in patients. Decl. Ex. 2, 120:23-121:23, 150:12-14; *see* also Decl. Ex.1, 1:14-24. As a result of these health concerns related to elevated ACA levels, the FDA and other regulatory authorities require that manufacturers test the levels of ACA before a batch can be released. As a result of these regulatory requirements, manufacturers of IGIV products desire to have ACA levels that are as low as possible, within the realm of available manufacturing technologies. Decl. Ex.1, 5:51-55; Decl. Ex. 2, 162:7-164:11, 168:2-169:5, 212:9-15. These efforts, mandated by the government to assure public health and safety, are not mere hypothetical, frivolous exercises, as Baxter's arguments suggest. Indeed, even

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D.I. 231, p.14, n.5; *see also* Decl. Ex. 2, 121:15-25, 196:13-19.

Fifth, regulatory agencies, including the FDA, require that ACA levels be measured for each product and set final product release specifications. So, for a given product, the manufacturer will choose a validated ACA assay, conduct tests using the assay to measure ACA, and present these test results to the FDA to suggest a release limit. Based on this information and extensive clinical data, the FDA will approve suggested release limits for the given product. Baxter's cited cases, *Datamize*[14] and *Halliburton*[15], are thus inapposite. These cases involved the terms "aesthetically pleasing" and "fragile gel", respectively. In both cases, the Court found these terms indefinite because they were both purely subjective, lacking an "objective anchor" that identifies the bounds of the claims for one skilled in the art. *Datamize*, 417 F.3d at 1350; *Halliburton*, 456 F. Supp. 2d at 817. In contrast, the term, "acceptable level suitable for intravenous administration" does not depend on the purely subjective opinion of one of ordinary skill in the art. Instead, clearly delineated objective standards exist for determining when ACA is reduced to an "acceptable level suitable for intravenous administration." These standards are derived from clinical evaluation of each IGIV product, and are ultimately formulated into numerical ACA final product release limits. The FDA approves ACA release limits for each IGIV product based on the results from clinical trials and approved ACA assays. In fact, the '191 specification provides examples of acceptable ACA levels for the patentee's own 5% and 10% IGIV solutions. Decl. Ex.1, 5:57-64. Thus, Baxter's argument that the '191 patent, like the patents in *Datamize* and *Halliburton*, provides no objective standard by which to measure

[14] *Datamize, LLC v. Plumtree Software, Inc.* 417 F.3d 1342 (Fed. Cir. 2005).
[15] *Halliburton Energy Servs., Inc. v. MI, LLC*, 456 F. Supp. 2d 811 (E.D. Tex. 2006).

acceptability is simply wrong. The term "acceptable level suitable for intravenous administration" is definite. *See* Decl. Ex. 2, 234:6-8.

2. The Term "Increased Level Of Anticomplement Activity" Is Definite.

The Court construed the term "increased level of anticomplement activity" in step a) to have its plain and ordinary meaning. D.I. 199, p.2. Baxter argues that "increased level" is indefinite because, assuming that the patent does not require an "increase" in ACA to an "unacceptable" level, the subsequent claim term in step b), "reduced to an acceptable level," has no meaning since the ACA level before incubation could already be "acceptable." Baxter further argues that "[i]t would be nonsensical to reduce ACA from an 'acceptable' level to an 'acceptable' level...." D.I. 231, pp.24-25. Baxter's argument thus hinges on its discredited reading of the claim term "increased level of [ACA]." The Court specifically rejected Baxter's construction, construing the term to have its plain and ordinary meaning, and noting that it may not "add a narrowing modifier before an otherwise general term that stands unmodified in a claim." D.I. 199, p.2, n.4 (citation omitted).[16] Baxter is thus attempting to take a second bite at the apple and rewrite the Court's claim construction.

Baxter contorts the '191 invention and Claim 1, proffering an argument that shoots wide of the mark. The '191 patent is directed to a method of reducing increased ACA to a level suitable for intravenous administration. For § 112 ¶ 2 purposes, all that is required is that one skilled in the art be able to discern claim scope. Step a) only requires an increase in ACA levels, and step b) requires a reduction in ACA levels – the scope of these terms is quite clear. And Baxter has admitted that only the ACA levels in the final product have to be acceptable. During claim construction, Baxter stated, "according to Claim 1, it is only the ACA levels in the ***final***

[16] Indeed, Baxter's expert, Dr. Snape, explicitly recognized that **REDACTED** . Decl. Ex. 8, 192:10-196:19; *see also* Decl. Ex. 6, 187:22-25. **REDACTED**

solution (i.e., after the incubation step, not after solvent/detergent treatment) that must be acceptable....That the final solution must have acceptable ACA does not require ***acceptable*** ACA levels prior to incubation..." D.I. 177, p.10 (emphasis added).[17] Baxter's current argument that release limits are not a standard because they are not established for intermediate products in Claim 1 (D.I. 231, p.20) is thus contradicted by Baxter's own claim construction brief. That the final solution must have acceptable ACA does not require ***unacceptable*** ACA levels prior to incubation. Thus, it is Baxter's argument that makes no sense because under Claim 1, acceptability in the final solution at the end of the process is the only fixed ACA level prescribed, and the only level that must be "acceptable," and this level is readily ascertainable and obtainable through reproducible approved procedures.

Moreover, Baxter's argument is contrary to reality. The '191 specification correctly recognizes that "[w]hile there is no strict rule for determining when the ACA level is low enough to be an acceptable level suitable for intravenous administration, IGIV preparations should have ACA levels as low as possible". Decl. Ex.1, 5:51-55; *see also* Decl. Ex. 2, 162:7-169:5.

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Id. at 170:4-175:18. It is inappropriate, as Baxter argues, to require an "increase" to a "given" unacceptable level, and as the prosecution history establishes, this very phrase was deleted from the claim. *See* JA88.

Baxter's further effort to create ambiguity by attempting to extract a snippet from the prosecution history (D.I. 231, p.26) is misguided. Baxter relies on out-of-context quotes from the

[17] D.I. 177 is Defendants' Reply to Plaintiffs' Opening Claim Construction Brief.

Board of Patent Appeals and Interferences decision addressing a § 103 rejection and having nothing to do with indefiniteness under § 112. *See Salazar v. Proctor & Gamble Co.*, 414 F.3d 1342, 1347 (Fed. Cir. 2005). Whether an increase in ACA resulting from solvent/detergent treatment is reduced in step b) is a question of fact that does not pertain to claim definiteness.

Based on the Court's claim construction (the plain and ordinary meaning of these claim terms), "increased" is sufficiently definite such that one skilled in the art would understand the bounds of the claim when read in light of the specification – an increase resulting from solvent/detergent treatment.

3. The Terms "Then Incubating The Solution Of Step a)" And "Increased Anticomplement Activity Of The Solution" Are Definite.

Baxter next argues that the terms "then incubating the solution of step a)" and "increased anticomplement activity of the solution" in step b) are indefinite. Again, Baxter attempts to reargue claim construction. The Court construed "increased anticomplement activity of the solution" to have its plain and ordinary meaning. D.I. 199, p.2. The Court construed the term "then incubating the solution of step a)" to mean "incubating a solution ***originating*** from step a) under conditions of controlled time, pH, temperature, and ionic strength, ***wherein additional steps*** may be performed prior to said incubating." *Id.* at p.3 (emphasis added).

Baxter now argues that because the additional processing steps allowed by the claim may result in a different "solution" with a different ACA level being incubated, it would no longer be "the increased ACA of ***the solution***" as required by step b). D.I. 231, pp.27-29 (emphasis added).

The Court's claim construction is again instructive. The Court construed "then incubating the solution of step a)" to specifically allow for additional processing steps before step b), consistent with the specification. The specification fully exemplifies intervening processing

steps. *See, e.g.*, D.I. 199, p.3 n.6. Baxter continues to argue that this Court should improperly read additional limitations into Claim 1. There is no requirement in Claim 1 that the ACA level immediately preceding the step b) incubation must be exactly the same as the level immediately following the solvent/detergent treatment of step a), and there is no basis here to impose such a requirement **REDACTED**

See Decl. Ex. 4, 420:4-8, 422:22-423:5, 429:6-431:7; Decl. Ex. 6, 179:20-180:5.

Dr. Ravetch explained that **REDACTED** Decl. Ex. 4, 429:6-431:7. Dr. Ravetch explained that **REDACTED** *Id.* at 423:2-13.

Dr. Ravetch also explained, contrary to Baxter's argument (D.I. 231, pp.3, 29), that **REDACTED** Decl. Ex. 4, 413:9-414:18. In accordance with the Court's claim construction, these intermediate solutions ***are*** "the solution of step a)" because they ***originate*** from step a). In essence, Baxter's argument that the "increase" is not the "increase" (D.I. 231, pp.27-28) is really a non-infringement argument and has no bearing on claim definiteness. Infringement is an issue that will be tried to the jury. For present purposes, the Court need only conclude that the terms are reasonably ascertainable by one skilled in the art and not indefinite as a matter of law. Instructively, Baxter's experts, Dr. Snape and Dr. Kindt, purportedly had no issue with intervening process steps when attempting to apply alleged prior art against Claim 1. The step b) terms "solution of step a)" and "solution" are not insolubly ambiguous.

VII. NUMEROUS ISSUES OF MATERIAL FACT PRECLUDE SUMMARY JUDGMENT ON THE CURRENT RECORD.

There are a number of issues of material fact which preclude summary judgment of invalidity for indefiniteness. These issues must be assessed in the context of the presumption of validity under 35 U.S.C. § 282 and that all inferences are drawn in favor of Plaintiffs under Federal of Civil Procedure Rule 56(c).

First, to the extent that different assays have varying degrees of validity depending on the step in the manufacturing process that is sampled and tested for ACA, and whether a particular test is used to determine an absolute or relative ACA value, a question of fact exists as to the proper methodology for the particular in-process sample. *See, e.g., Verve*, 395 F. Supp. 2d at 569 (question of what methodology should be used is a question of fact for the jury when decision is not required by claim language). In the case of relative values, variability in assays plainly does not equate to indefiniteness. The assay accurately measures relative values of a particular product. However, any remaining question is a question of fact to be decided by the jury.

Second, the determination of one of ordinary skill in the art through which Claim 1 must be evaluated is a disputed issue of material fact. As urged by Plaintiffs, one of ordinary skill in the art is one or more scientists, each with an earned doctoral degree and several years of postdoctoral experience in the fields of antibody biochemistry, protein purification or process manufacturing, and/or clinical treatment of humans using IGIV. *See* Decl. Ex. 10, p.3. Baxter's proposed definition of one skilled in the art is admittedly at odds with Plaintiffs' (D.I. 231, p.9 n.3). We believe this difference is a material fact because Baxter's proposed diminished level of education would allow for a manufacturing technician to qualify as one of ordinary skill in the art, and Baxter's indefiniteness arguments urge that Claim 1 must either be construed like a manufacturing specification with precise numeric elements and a single method of measuring

them or it is invalid as indefinite. Plaintiffs' position is that one skilled in the art has a materially higher level of education (*e.g.* a doctoral degree including a Ph.D. and/or an M.D.) and thus can use the '191 teachings to readily understand the scope of Claim 1 to develop manufacturing processes and protocols understandable by Baxter's "technicians," and would know how to properly apply each of the elements in Claim 1. *See Playtex Prods, Inc. v. Proctor & Gamble Co.*, 400 F.3d 901, 907 (Fed. Cir. 2005) (patent language need not describe the claimed invention "at the level of manufacturing specification").

Third, whether ACA levels from different assays must be compared to a single standard (D.I. 231, pp.15-19), and whether such a standard even exists, gives rise to numerous factual issues of fact dependent on evaluation of expert testimony.

Fourth, whether FDA release limits provide such a standard (*id.* at pp.20-23) also engenders an issue of fact dependent on expert testimony.

Fifth, the role of adverse events in the establishment of FDA-approved ACA specifications (*id.* at pp.23-24) is another factual issue that turns on expert testimony.

These issues of fact alone preclude summary judgment.

VIII. CONCLUSION

Baxter has failed to prove by clear and convincing evidence that there are no genuine issues of material fact, and that the '191 patent is invalid for indefiniteness. Plaintiffs have proffered substantial evidence establishing the need for expert testimony and the resolution of fact issues raised by Baxter. For the foregoing reasons, Plaintiffs respectfully request that this Court deny Baxter's motion for summary judgment of invalidity of the '191 patent for indefiniteness.

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CERTIFICATE OF SERVICE

I hereby certify on this 29th day of March, 2007 I electronically filed the foregoing Plaintiffs' Brief in Opposition to the Motion for Summary Judgment filed by Baxter International Inc. and Baxter Healthcare Corporation with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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I also hereby certify that a true copy of the foregoing document was served upon the following in the manner indicated on March 29, 2007.

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